

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

BARBARA KAISER and	)	
ANTON KAISER,	)	MDL No. 2327
	)	In Re Ethicon, Inc., Pelvic Repair System
Plaintiffs,	)	Products Liability Litigation
	)	
v.	)	
	)	CIVIL ACTION FILE NO. <u>2:12-0887</u>
JOHNSON & JOHNSON and	)	
ETHICON, INC.,	)	
	)	
Defendants.	)	

**COMPLAINT**

NOW COME the Plaintiffs, BARBARA KAISER and ANTON KAISER, by and through their attorneys, COSTELLO, MCMAHON, BURKE & MURPHY, LTD., and as Plaintiffs herein, and hereby file this Complaint, showing the Court as follows:

**PARTIES, JURISDICTION AND VENUE**

1. Plaintiffs are citizens of the State of Indiana.
2. Defendant, JOHNSON & JOHNSON, is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of JOHNSON & JOHNSON as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.
3. Defendant, ETHICON, INC., is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of ETHICON, INC., as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.
4. Plaintiffs are seeking damages in excess of \$75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

5. Together with Defendant, ETHICON, INC., Defendant, JOHNSON & JOHNSON, marketed, sold and distributed Gynecare Prolift Total Repair System PFRT01 (hereinafter, “Prolift”) to Plaintiff, BARBARA KAISER’s health care providers in the State of Indiana. Having transacted business within the State of Indiana giving rise to Plaintiffs’ causes of actions herein, Defendant, JOHNSON & JOHNSON, is subject to the personal jurisdiction of this Court pursuant to the Indiana Long Arm Statute.

6. A substantial part of the events and omissions giving rise to Plaintiffs’ causes of action occurred in the Northern District of Indiana.

7. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the Northern District of Indiana.

### **FACTUAL BACKGROUND**

1. On and before January 2009, Defendants, JOHNSON & JOHNSON and ETHICON, INC.. (hereinafter, “Defendants”) marketed and sold a medical device known as Prolift, for the treatment of female pelvic organ prolapse.

2. Defendants designed, manufactured, labeled, marketed, sold and distributed Prolift, including that which was implanted into Plaintiff, BARBARA KAISER, giving rise to Plaintiffs’ causes of action herein.

3. Defendants have been, and continue to, market their Prolift to the medical community and to patients as a safe, effective, and reliable medical device which is implanted via safe, effective, minimally invasive surgical techniques for the treatment of pelvic organ prolapse, and as safer and more effective as compared to other products and procedures.

4. Defendants have marketed and sold their Prolift to the medical community and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and often include the provision of valuable consideration and benefits to health care providers. Defendants also utilize documents, brochures, websites, and telephone information lines, offering exaggerated and misleading information as to the safety and utility of their Prolift.

5. Contrary to Defendants' representations and marketing to the medical community and to patients, Defendants' Prolift has high failure, injury, and complication rates; the product fails to perform as intended; its use requires frequent and often debilitating re-operations; and it has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, BARBARA KAISER.

6. On July 13, 2011, the FDA issued a safety communication to warn health care providers and patients that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**. . . . Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

7. During a hearing in September 2011 in Gaithersburg, Maryland, an FDA review team concluded there was insufficient scientific evidence as to the safety and efficacy of transvaginal surgical mesh used to treat pelvic organ prolapse, including Defendants' Prolift.

8. Defendants have consistently underreported and withheld information about their Prolift's propensity to fail and cause injury and complications, and have misrepresented the

efficacy and safety of the products through various means and media, actively and intentionally misleading the medical community, patients, and the public at large.

9. Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers, and patients, into believing their Prolift is safe and effective, leading to the prescription for, and implantation of, their Prolift into Plaintiff, BARBARA KAISER, and numerous other women.

10. Defendants failed to perform or rely on proper and adequate testing and research to determine and evaluate the risks and benefits of their Prolift.

11. Defendants failed to design and establish a safe, effective procedure for removal of their Prolift in the event of a failure, injury, or complication associated with the device.

12. Feasible and suitable alternatives for the treatment of pelvic organ prolapse as compared to the Prolift have existed at all times relevant hereto.

13. On or about January 27, 2009, Plaintiff, BARBARA KAISER, was implanted with Defendants' Prolift during surgery performed by Gregory T. Bales, M.D., at Community Hospital in Munster, Indiana. On or about September 13, 2011, Plaintiff, BARBARA KAISER, first learned from Raphael Albert, M.D., that her complaints of low pelvic pain could be related to the Prolift implant.

14. Defendants' Prolift mesh was implanted into Plaintiff, BARBARA KAISER, to treat her pelvic organ prolapse, the use for which the product was designed, marketed and sold.

15. Defendants' Prolift was implanted into Plaintiff, BARBARA KAISER, and was therefore utilized and implanted in a manner foreseeable to Defendants.

16. Defendants have provided incomplete, insufficient, and misleading training and information regarding the Prolift to physicians to increase the number of physicians utilizing the product, and thus increase sales of the product, which has also lead to the dissemination of inadequate and misleading information to patients, including Plaintiff Barbara Kaiser.

17. As a result of having Defendants' Prolift implanted into her, Plaintiff, BARBARA KAISER, has experienced significant mental and physical pain and suffering, has sustained permanent injury, will likely undergo corrective surgery, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and has endured impaired physical relations with her husband, Plaintiff, ANTON KAISER.

18. Despite Defendants' knowledge of similar catastrophic injuries, conditions, and complications caused by their Prolift, Defendants have, and continue to, manufacture, market, and sell the products, while continuing to inadequately warn, label, instruct, and disseminate information regarding the product, both prior to and after the marketing and sale of the product implanted into Plaintiff, BARBARA KAISER.

## **CAUSES OF ACTION**

### **COUNT I: NEGLIGENCE**

1. Plaintiffs incorporate into Count I by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants had a duty to individuals, including Plaintiff, BARBARA KAISER, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling their Prolift.

3. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling their Prolift.

4. As a direct and proximate result of Defendants' negligence, Plaintiff, BARBARA KAISER, was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

#### **COUNT II: STRICT LIABILITY – DESIGN DEFECT**

1. Plaintiffs incorporate into Count II by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants' Prolift implanted into Plaintiff, BARBARA KAISER, was not reasonably safe for its intended use and was defective as a matter of law with respect to its design.

3. As a direct and proximate result of Defendants' Prolift's aforementioned defects, Plaintiff, BARBARA KAISER, was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

4. Defendants are strictly liable to Plaintiff, BARBARA KAISER, for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

#### **COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT**

1. Plaintiffs incorporate into Count III by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants' Prolift implanted into Plaintiff, BARBARA KAISER, was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.

3. As a direct and proximate result of Defendants' Prolift's aforementioned defects, Plaintiff, BARBARA KAISER, was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

4. Defendants are strictly liable to Plaintiff, BARBARA KAISER, for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

#### **COUNT IV: STRICT LIABILITY – FAILURE TO WARN**

1. Plaintiffs incorporate into Count IV by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants' Prolift implanted into Plaintiff, BARBARA KAISER, was not reasonably safe for its intended use and was defective as a matter of law due to its lack of appropriate and necessary warnings.

3. As a direct and proximate result of Defendants' Prolift's aforementioned defects, Plaintiff, BARBARA KAISER, was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

4. Defendants are strictly liable to Plaintiff, BARBARA KAISER, for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

**COUNT V: BREACH OF EXPRESS WARRANTY**

1. Plaintiffs incorporate into Count V by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants made assurances to the general public, hospitals and health care professionals that their Prolift was safe and reasonably fit for its intended purpose.

3. Plaintiff, BARBARA KAISER, chose Defendants' Prolift based upon Defendants' warranties and representations regarding the safety and fitness of the product.

4. Plaintiff, BARBARA KAISER, reasonably relied upon Defendants' express warranties and guarantees that their Prolift was safe, merchantable, and reasonably fit for its intended purpose.

5. Defendants breached these express warranties because their Prolift implanted into Plaintiff, BARBARA KAISER, was unreasonably dangerous and defective and not as Defendants had represented.

6. Defendants' breaches of their express warranties resulted in the implantation of an unreasonably dangerous and defective product into Plaintiff, BARBARA KAISER's body, placing said Plaintiff's health and safety in jeopardy.

7. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff, BARBARA KAISER, was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

**COUNT VI: BREACH OF IMPLIED WARRANTY**

1. Plaintiffs incorporate into Count VI by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants impliedly warranted that their Prolift was merchantable and was fit for the ordinary purpose for which it was intended.

3. When Defendants' Prolift was implanted into Plaintiff, BARBARA KAISER, to treat her pelvic organ prolapse, the product was being used for the ordinary purpose for which it was intended.

4. Plaintiff, BARBARA KAISER, relied upon Defendants' implied warranty of merchantability in consenting to have Defendants' Prolift implanted into her.

5. Defendants breached this implied warranty of merchantability because their Prolift implanted into Plaintiff, BARBARA KAISER, was neither merchantable nor suited for its intended use as warranted.

6. Defendants' breach of their implied warranty resulted in the implantation of an unreasonably dangerous and defective product into Plaintiff, BARBARA KAISER's body, placing said Plaintiff's health and safety in jeopardy.

7. As a direct and proximate result of Defendants' breach of the aforementioned implied warranty, Plaintiff, BARBARA KAISER, was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

**COUNT VII: LOSS OF CONSORTIUM**

1. Plaintiffs incorporate into Count VII by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. As a direct and proximate result of the above-described injuries sustained by Plaintiff, BARBARA KAISER, her husband, Plaintiff, ANTON KAISER, has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

**COUNT VIII: PUNITIVE DAMAGES**

1. Plaintiffs incorporate into Count VIII by reference all of the above paragraphs of this Complaint as if fully set forth herein.

2. Defendants knew or should have known that their Prolift was inherently more dangerous with respect to the risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which were permanent and lasting in nature.

3. Defendants misrepresented facts concerning the safety of their Prolift.

4. Defendants' misrepresentations included withholding material information from the medical community and the public, including Plaintiff, BARBARA KAISER, regarding the safety and efficacy of their Prolift.

5. Defendants knew and recklessly disregarded the fact that their Prolift caused debilitating and potentially lethal complications with greater frequency than safer alternative methods and/or products used to treat pelvic organ prolapse.

6. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by their Prolift.

7. Notwithstanding the foregoing, Defendants continue to aggressively market their Prolift to consumers, without disclosing the true risks associated with the products.

8. Defendants knew of their Prolift's defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, BARBARA KAISER.

9. Defendants continue to conceal and/or fail to disclose to the public, including Plaintiff, BARBARA KAISER, the serious complications associated with the use of their Prolift to ensure continued and increased sales of the products.

10. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding \$75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFFS DEMAND A TRIAL BY JURY.

March 6, 2012.

Respectfully submitted,

COSTELLO, MCMAHON BURKE & MURPHY, LTD.

By: /s/ Thomas O. Plouff  
Attorney for Plaintiff

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